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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,498	09/20/2006	Tanja Bendele	903-196 PCT/US	8290
23869 7590 03/11/2009 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER RUMP, RICHARD M	
			ART UNIT 1793	PAPER NUMBER
			MAIL DATE 03/11/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,498	<b>Applicant(s)</b> BENDELE ET AL.	
	<b>Examiner</b> Richard M. Rump	<b>Art Unit</b> 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

Claims 1-8, 10-19 are pending and presented for examination. Claims 1, 3 and 16 stand amended, claim 9 is canceled and claims 18 and 19 were added by Applicant's amendment on 27 January 2009.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-6, 8, 10, 12, 16-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaupp, "Environmentally Protecting Reactive Milling" (Provided by Applicant).**

Regarding claims 1-2, 10, 12 and 16-17, Kaupp discloses a method of milling 0.8 g of o-dichlorobenzene and 1 g of tetrabutyltin with 200g of quartz sand at a rate of 300 rpm (page 6, first full paragraph) at a rate of 100 rpm (last line of page 2) with argon (page 6, line 12). The velocity used is 14 m/s (page 2, line 3).

Regarding claim 3, given a 2L milling (figure 1 caption) system operating at 1800 rpm this would yield 453g of force, reading on the "... and higher" limitation of instant claim 3.

Regarding claim 4, there would inherently be some crystallization given internal heating and subsequent cooling going on from the milling process.

Regarding claim 5, particular attention is pointed to figure 3 of Kaupp which shows the collision and energy transfer. It would be at a minimal envisaged that there would be interfaces at the solid given that during milling, it is a surface-surface contact.

Regarding claims 6 & 8, Kaupp discloses a milling operation between ninhydrin and solid amino acid L-proline with steel balls results in azomethine imine which is a zwitterion and is a pure-phase (page 7, lines 1-12) under similar conditions.

Furthermore, as the material cools post milling, it can at a minimal be envisaged that there will be some level of phase transformation and with it polymorphism. As such there can be a degree of phase-pure and incongruent phases contained therein.

Regarding claim 19, given the combination of ninhydrin and L-proline to produce azomethine imine zwitterion, this can be taken as a co-crystal given its standard definition in the art which is a multi-component crystal. Since this is a pure-phase material and will contain some crystallinity, it can be taken as a multi-component crystal.

**Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Matzger (US PG Pub No. 20030113802).**

Regarding claim 18, Matzger discloses the milling of drug materials to produce a pharmaceutical product ([0030]) using a high-throughput system ([0002]).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaupp as applied to claim 1 above and further in view of Matzger.**

Regarding claim 7, while Kaupp is silent to the usage of amorphous polymers, it would be in the scope of the skilled artisan to perform the pharmaceutical milling process of Matzger ([0012]) as it deals with organic molecules like Kaupp.

**Claims 11, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaupp.**

Regarding claim 11, the order of steps or differences between a continuous and semi-/non- continuous operation is not patentable (See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946)).

Regarding claims 13-14, while Kaupp is silent as to the temperature and pressure, these are routinely controlled through routine experimentation (See MPEP 2144.05) as functions of the milling speed (for temperature) and degree of wanted crystallinity.

***Response to Arguments***

The 112(2) rejections of claims 2, 3 and 16 are withdrawn due to amendment.

Applicant's arguments, see pages 1-5, filed 27 January 2009, with respect to the rejection(s) of claim(s) 1-18 under 102(b), 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kaupp. Since Applicant provided Kaupp as evidentiary reference for "high kinetic energy ... milling", this is being taken as an admission on the record that the cited art would read upon the 'high' limitations of claims 1 and its dependants, except for claim 3, which further limits.

### ***Conclusion***

Claims 1-8, 10-19 have been rejected.

Applicant is encouraged in filing a request for continued examination to specifically claim the organic molecules as the scope of claim 1. This is however, not a notice of allowability as no search has been conducted and would be required to determine patentability.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard M. Rump whose telephone number is (571)270-5848. The examiner can normally be reached on Monday through Friday 7:00 AM-4:30 PM (-5 GMT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on (571)272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/R. M. R./  
Examiner, Art Unit 1793

/Stuart Hendrickson/  
Primary Examiner, Art Unit 1793